NIH/FDA Next-Generation Sequencing and Radiomics Workshop: Resource Requirements for Acceleration of Clinical Applications Including AI

All times are listed in Eastern Daylight Time.

Wednesday, September 29th – Genomics

12:30 pm	Welcome and Opening Remarks
	Norman Sharpless, MD, National Cancer Institute, and Jeffrey Shuren, MD, JD, U.S. Food and Drug Administration
12:45 pm	Goals of the Workshop Lyndsay Harris, MD, National Cancer Institute
12:55 pm	Keynote Presentation NCI Research Data Commons Anthony Kerlavage, Ph.D., National Cancer Institute
1:25 pm	10-minute Break
1:35 pm	Genomics Plenary Session Reference Samples to Compare Next Generation Sequencing Test Performance: The Sustainable Predictive Oncology Therapeutics and Diagnostics (SPOT/Dx) Diagnostic Quality Assurance Pilot John Pfeifer, MD, PhD, Washington University
1:55 pm	Accelerating Genomics into the Clinic Euan Ashley, MD, PhD, Stanford University
2:15 pm	Medical Device Innovation Consortium (MDIC) Somatic Reference Sample Project Carolyn Hiller, MBA, Medical Device Innovation Consortium, and Justin Zook, PhD, National Institute of Standards and Technology
2:35 pm	Summary of Genomics RFI Comments and Charge to Break-Out Group Kristofor Langlais, Ph.D., U.S. Food and Drug Administration
2:50 pm	Genomics Break-Out Group Session Facilitated by Birgit Funke, PhD, PACMG, Sema4
3:50 pm	10-minute Break
4:00 pm	Genomics Break-Out Group Report Out Birgit Funke, PhD, PACMG, Sema4

Thursday, September 30th – Radiomics

9:45 am	
	Lalitha Shankar, MD, PhD, National Cancer Institute
	Radiomics Plenary Session
10:00 am	Clinical Utility of Al Tools in Brain Tumors
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	Resources needed to advance AI/ML in cancer imaging, COVID-19, and
10:20 am	other diseases: data collection, annotations, harmonization, metrology, and
	sequestered datasets
	Maryellen Giger, PhD, University of Chicago
10:40 am	Summary of Radiomics RFI Comments and Charge to Break-Out Group
	Kristofor Langlais, Ph.D., U.S. Food and Drug Administration
10:55 am	Radiomics Break-Out Group Session
	Facilitated by Curtis Langlotz, MD, PhD, FACMI, Stanford University
11:55 am	10-minute Break
12:05 pm	Radiomics Break-Out Group Report Out
	Curtis Langlotz, MD, PhD, FACMI, Stanford University